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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,643	01/09/2006	Richard L. Arden	ARC-100-PCT-US	2298

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EXAMINER

BLATT, ERIC D

ART UNIT	PAPER NUMBER
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3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,643	Applicant(s) ARDEN, RICHARD L.	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites that the enveloping lip and first portion are formed from a non-toxic material, that the lip is made of a flexible material, and the first portion is made of a hard material. The first recitation appears to indicate that the lip and first portion are made from the same material while the following recitations seem to require that they are made from different materials. It is unclear what this language intends. For present purposes of examination, this language is taken to suggest that a single material may be considered to be both flexible and hard.

In claim 20, the paragraph beginning, "a second tube element," recites "the element" where more than one element has antecedent basis and "a rearward end" where a rearward end has been previously recited. To clarify the language of claim 20, Examiner suggests consistently referring to the first tube element and its portions using the word 'first' in the element recitations ("the first tube element," "the first forward end," "the first rearward end," "the first central body portion," etc.) and consistently referring to

the second tube element and its portions using the word 'second' in the element recitations.

Claim Rejections - 35 USC § 103

Claims 1-7, 9-10, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769) in view of Bruneau et al. (US 6,579,298).

Clement discloses an instrument for extracting foreign bodies from a cavity of a human comprising an elongated tubular structure, said tubular structure defining distal and proximal ends and a single passageway (Fig. 2, #28) between the ends, the distal end portion being generally positionable within the canal or passage, (see Fig. 15) the end portion including an enveloping lip sized to envelop and be engaged by a foreign body drawn there within, (see Fig. 15, #238 and 239) and the proximal end being removably connectible to a source of negative pressure, a lowering of the pressure in the passageway operating to suction and captivate the foreign particle into the distal end. (col. 7, ln 18-20 and ln 43-51; col. 6, ln 41-46) There is a closure valve in operable relation with the passageway for adjusting the amount of air that is drawn between the distal and proximal ends of the tubular structure (co. 4, ln 54-57; col. 5, ln 14-19; col. 6, ln 5-14 and ln 47-49).

The valve (Fig. 2, #12) includes an inlet (30) and an outlet (32), and the tubular structure includes first (24) and second (26) portions. The first portion includes a rearward end (Fig. 2, #30) and said distal end (Fig. 15, #239), and said rearward end is

connectible to the inlet (30) of said valve. The second (26) portion includes a forward end (see Fig. 2) and said proximal end (see Fig. 1), and said forward end is connectible to the outlet (32) of said valve (col. 7, ln 43-51). Said first portion (24) is curvilinear (see Fig. 15 and 28) and the rearward and distal ends thereof are angularly offset and disposed at an angle θ relative to one another (col. 2, ln 2-4). Said valve includes a valve body (Fig. 2, #12) having said inlet (30) and outlet (32), a passageway (see Fig. 2) extending between said inlet and outlet and connecting the passages in said first (24) and second portions (26), and a valve stem having a passageway for varying the amount of flow permitted through the passageway of said valve body and passages of said tube structure (col. 4, ln 49-60; col. 5, ln 14-19; col. 6, ln 5-10). Said valve stem is mounted for rotation relative to the valve body and positions the passageway thereof in the passageway of said valve body, wherein rotation of the stem causes the passageway in said stem to move into and out of register with the valve passageway and change the amount of air that is permitted to drawn into and through the tubular structure (col. 4, ln 49-60; col. 5, ln 14-19; col. 6, ln 5-14).

Clement thus discloses all elements of claims 1-3, 6, 7, 9, 10, 13, 15 and 16 except for the distal end portion having a frusto-conical end portion flaring outwardly at the distal end and including an annular enveloping lip. Bruneau teaches that it was well known in the art to provide the distal end of an aspirating tube with a frusto-conical end portion that flares outwardly to an annulus at the distal end. (Figure 7) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Clement by providing a frusto-conical end portion that flares outwardly to

an annulus at its distal end as taught by Bruneau in order to increase the effectiveness of the aspiration by increasing the cross-sectional area at the end of the aspirating tube. The annulus at the distal end of the flared portion may be considered to comprise an annular enveloping lip. Regarding claims 9 and 10, said lip would be formed integrally with the distal end of tube 24 and would be made from the same hard flexible plastic from which the rest of tube 24 is made.

Regarding claims 4 and 5, Clement does not explicitly disclose that the angle θ is about 130° to about 140° . It would have been obvious to one of ordinary skill in the art at the time of the invention to have the suction conduit curved down from an angle θ of about 130° to about 140° , since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 8, 12, 14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769) in view of Bruneau et al. (US 6,579,298) as applied to claims 1-7, 9-10, 13, 15 and 16 above, and further in view of Kieffer, III et al. (US 4,380,998).

Regarding claims 8, 17 and 18, Clement teaches the above limitations as shown, but does not explicitly disclose that said enveloping lip is removably mounted to said distal end or that the annular enveloping lip (the distal tip of the modified tube 24) comprises a more flexible material than the material from which the tube 24 is made. Kieffer however, in Figures 1 and 2, items #40 and #42 discloses these limitations (col.

3, ln 20-25, col. 3, ln 25-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the removable soft tip speculum of Kieffer, because using a soft removable speculum with a nasally or auditorially insertable tube having a hard body can protect the ear canal and by interchanging different tip sizes to fit different ear sizes helps to form a conforming seal to prevent air from leaking when suction is applied (Kieffer, col. 1, ln 24-25; col. 2, ln 5-13). Regarding claim 19, the modified lip is coupled to the tube to form an integral functional unit and is thus considered to be integrally formed with the distal end.

Regarding claims 12, 14 and 20, Clement and Kieffer teach all elements of said claims as previously discussed except for a magnifying lens, the lens being affixed to the first portion to enable the user to see within the cavity and ensure that the lip envelops the foreign object. Kieffer, III et al. however, in Figures 1 and 2, item #31 disclose this limitation (col. 3, ln 6-8). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the magnifying lens otoscope of Kieffer, because using a lens in conjunction with the suction tube would allow the device to be used as a diagnostic instrument (Kieffer, col. 3, ln 11) by providing a visual indication of the placement of tip with respect to the foreign object in the ear.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769) in view of Bruneau et al. (US 6,579,298) as applied to claim 10

above, and further in view of and Kieffer, III et al. (US 4,380,998) and Ehmsen et al. (US 5,377,668).

Clement teaches all elements of claim 11 except for the cross-section of said first portion expanding outwardly in extending in opposite axial directions from a central body portion towards the distal and proximal ends, and an exterior section of the second portion being provided with convolutions to enable easy and secure gripping.

Kieffer discloses a related apparatus comprising a tube 40 that expands outwardly in extending in opposite axial directions from a central body portion towards the distal and proximal ends. (Figures 1 and 2) It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the frustoconical tip speculum of Kieffer, because using a tip with outwardly expanding towards the distal and proximal ends can allow the ear canal to be held in a dilated condition suitable for examination, which is also capable of conforming to the contour of the ear canal to provide a good pneumatic seal (Kieffer, col. 1, In 21-23 and In 61-64).

Ehmsen discloses an exterior section of a gripping portion being provided with convolutions 52 to enable easy and secure gripping. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the second portion 26 with convolutions in order to improve comfort and security when gripping the device as taught by Ehmsen.

Response to Arguments

Applicant's arguments filed 10-9-2009 have been fully considered but they are not persuasive.

Applicant argues that the distal end in Figure 15 of Clement is not generally frusto-conically shaped as recited in claim 1. As discussed in the body of the rejection, providing an aspirating tube with a frusto-conically shaped distal tip as claimed was well known in the art for expanding the cross-section of the tube at the aspirating tip. (See at least Figure 7 of US Patent No. 6,579,298 to Bruneau et al.) It would have been obvious to one skilled in the art to provide Clement device with such a frusto-conically shaped distal tip in order to achieve these benefits. Such a tip would have a distal portion that could be considered to comprise an annular enveloping lip as claimed.

Applicant additionally argues that Clement discloses a device having two passageways while the claims recite only a single passageway. Without addressing the number of passageways shown in the Clement device, Examiner notes that as long as the Clement device comprises at least one passageway, it meets the limitation that there is a "single passageway" since this recitation does not preclude the presence of additional passageways. Passageway 28 as shown in Figures 1 and 2 of Clement comprises a single passageway.

Applicant also argues that Clement fails to disclose a lip being integrally formed with the distal end of the tube. For most purposes in the body of the rejection, the distal tip of the tube is taken to define a lip. Said lip is obviously integrally formed with the

distal end of the tube. Examiner also notes that elements may be broadly considered to be integral with one another if they exist together as an integral functional unit.

With regard to claim 10, Applicant argues that Clement fails to disclose that the lip is formed of a flexible material and the first portion 24 is formed of a hard material. It appears that the first portion 24 is formed from a relatively rigid plastic material. (The device is disclosed as being made from plastics, and Col. 7, Lines 3-6 discloses that the alternate embodiment shown in Figures 28-30 illustrates that the conduit does not have to be formed from a rigid piece, thereby suggesting that the conduit in previous embodiments is relatively rigid.) For purposes of claim 10, the distal tip of the modified conduit 24 is considered to comprise the enveloping lip. Thus, both the first portion 24 and the enveloping lip comprise a hard plastic. Plastics inherently have at least some degree of flexibility.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3734

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734